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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

OZAWA et al.

Serial No.: Unassigned

Group Art Unit: Unassigned

Filing Date: Even Date Herewith

Examiner: Unassigned

Title: ADENO-ASSOCIATED VIRUS-MEDIATED DELIVERY OF  
ANGIOGENIC FACTORS

### INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The information listed below may be material to the examination of the above-identified application. Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is respectfully requested to make this information of official record in the application. The information includes:

United States Patent No. 5,858,351 issued Jan. 12, 1999 to Podsakoff *et al.*;

United States Patent No. 6,211,163 issued Apr. 3, 2001 to Podsakoff *et al.*;

Asahara, *et al.*, "Accelerated restitution of endothelial integrity and endothelium-dependent function after phVEGF165 gene transfer," *Circulation* 94:3291-3302 (1996);

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Baumgartner, *et al.*, "Constitutive expression of phVEGF165 after intramuscular gene transfer promotes collateral vessel development in patients with critical limb ischemia," *Circulation* 97:1114-1123 (1998);

Ferrara, *et al.*, "Molecular and biological properties of the vascular endothelial growth factor family of proteins," *Endocr. Rev.* 13:18-32 (1992);

Guzman, *et al.*, "Efficient gene transfer into myocardium by direct injection of adenovirus vectors," *Circ. Res.* 73:1202-1207 (1993);

Hariawala, *et al.*, "VEGF improves myocardial blood flow but produces EDRF-mediated hypotension in porcine hearts," *J. Surg. Res.* 63:77-82 (1996);

Henry, *et al.*, "Double blind, placebo controlled trial of recombinant human vascular endothelial growth factor—the VIVA Trial," *J. Am. Coll. Cardiol.* 33:384A (1999);

Hojo, *et al.*, "Expression of vascular endothelial growth factor in patients with acute myocardial infarction," *J. Am. Coll. Cardiol.* 35:968-973 (2000);

Isner, *et al.*, "Clinical evidence of angiogenesis after arterial gene transfer of phVEGF165 in patient with ischaemic limb," *Lancet.* 348:370-374 (1996);

Leung, *et al.*, "Vascular endothelial growth factor is a secreted angiogenic mitogen," *Science* 246:1306-1309 (1989);

Losordo, *et al.*, "Gene therapy for myocardial angiogenesis: initial clinical results with direct myocardial injection of phVEGF165 as sole therapy for myocardial ischemia," *Circulation* 98:2800-2804 (1998);

Mack, *et al.*, "Salvage angiogenesis induced by adenovirus-mediated gene transfer of vascular endothelial growth factor protects against ischemic vascular occlusion," *J. Vasc. Surg.* 27:699-709 (1998);

Mack, *et al.*, "Biologic bypass with the use of adenovirus-mediated gene transfer of the complementary deoxyribonucleic acid for vascular endothelial growth factor 121

#### REFERENCES CITED AND DISCUSSED

Maeda, *et al.*, "Gene transfer into vascular cells using adeno-associated virus (AAV) vectors," *Cardiovasc. Res.* 35:514-521 (1997);

Maeda, *et al.*, "Efficient gene transfer into cardiac myocytes using adeno-associated virus (AAV) vectors," *J. Mol. Cell Cardiol.* 30:1341-1348 (1998);

Maeda, *et al.*, "Adeno-Associated Virus-Mediated Vascular Endothelial Growth Factor Gene Transfer in to Cardiac Myocytes," *J. Cardiovasc. Pharmacol.* 36:438-443 (2000);

Magovern, *et al.*, "Direct in vivo gene transfer to canine myocardium using a replication-deficient adenovirus vector," *Ann. Thorac. Surg.* 62:425-433 (1996);

Muhlhauser, *et al.*, "VEGF165 expressed by a replication-deficient recombinant adenovirus vector induces angiogenesis in vivo," *Circ. Res.* 77:1077-1086 (1995);

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Shibuya, *et al.*, "Nucleotide sequence and expression of a novel human receptor-type tyrosine kinase gene (flt) closely related to the fms family," *Oncogene* 5:519-524 (1990);

Shulick, *et al.*, "In vivo gene transfer into injured carotid arteries. Optimization and evaluation of acute toxicity," *Circulation* 91:2407-2414 (1995);

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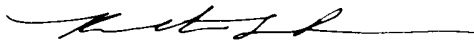
This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

Date:

8/17/01

By:



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